UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

Classen Immunotherapies, Inc.,	*	
Plaintiff,	*	Civ. No.: RDB-04-3521
v.	*	
Elan Pharmaceuticals, Inc.,	*	
Defendants.	*	

* * * * * * * * * * * * * *

MEMORANDUM OPINION

This case is again before this court on remand from the United States Court of Appeals for the Federal Circuit. (ECF No. 231.)[1] Currently pending is defendant Elan Pharmaceuticals, Inc.'s ("Elan" or "Defendant") Motion for Summary Judgment of Non-Infringement ("Elan's Motion") (ECF No. 249). Plaintiff Classen Immunotherapies, Inc. ("Classen" or "Plaintiff") has filed an Opposition to Elan's Motion ("Classen's Opposition") (ECF No. 250), and Elan has filed a Reply to Classen's Opposition ("Elan's Reply") (ECF No. 251). The Court conducted a hearing on the parties' submissions on September 22, 2016. (ECF No. 252.) For the reasons set forth below, Elan's Motion is GRANTED.

[1] This case was transferred to the undersigned on January 22, 2016 following Judge Quarles' retirement from the bench.

FACTUAL AND PROCEDURAL BACKGROUND

The pertinent factual and procedural history of this case was set forth by the Federal Circuit in its decision remanding this case to this Court. *Classen Immunotherapies, Inc. v. Elan Pharm., Inc.*, 786 F.3d 892, 894–95 (Fed. Cir. 2015).

> "Classen owns the '472 patent, which is directed to a method for accessing and analyzing data on a commercially available drug to identify a new use of that drug, and then commercializing that new use. Classen sued Elan in 2004, alleging that Elan infringed the '472 patent when it studied the effect of food on the bioavailability of Skelaxin, used the clinical data to identify a new use of the drug, and commercialized the new use. *Classen,* 466 F.Supp.2d at 624. Elan moved for summary judgment of noninfringement. The district court granted the motion in 2006, finding Elan protected by the safe harbor provision of § 271(e)(1)[2] because Elan submitted its clinical data to the FDA with its citizen petition and sNDA, and thus its activities were "reasonably related to the submission of information" under the Federal Food, Drug, and Cosmetic Act ("FDCA"). *Id.* at 625.
>
> "The lawsuit was then stayed pending an *ex parte* reexamination of the '472 patent, during which the PTO cancelled 107 of the 137 originally issued claims. Of the remaining claims, only claims 36, 42, 48–50, 59, 73–76, 84, 131, and 135 were asserted against Elan. Prior to issuing the reexamination certificate, the PTO Examiner stated, as reasons for patentability, that the "prior art of record fails to teach or fairly suggest the limitation of 'a manufacturer or distributor of the product must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one new adverse event associated with exposure to or use of the product.'"
>
> …
>
> "After the reexamination certificate issued in 2010, Classen filed a motion in the district court seeking to lift the stay and to vacate the 2006 summary judgment. Classen argued that our decision in *Classen Immunotherapies, Inc. v. Biogen IDEC,* 659 F.3d 1057 (Fed. Cir. 2011) warranted reconsideration of the summary judgment because we held in *Biogen* that certain post-approval routine submissions to the FDA are outside the safe harbor of § 271(e)(1). In response, the district court lifted the stay but denied reconsideration of its 2006 decision. The court concluded that Elan was protected by the safe harbor under both *Biogen* and our subsequent decision in *Momenta*

[2] 35 U.S.C. § 271(e)(1). Footnote added.

> *Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.,* 686 F.3d 1348 (Fed. Cir. 2012). The court reasoned that unlike *Biogen,* where the post-approval submissions were routine, Elan's submissions to the FDA were "not routine" because they were necessary to update the Skelaxin product label and to change the FDA-approval process for generic versions of Skelaxin. *Classen,* 981 F.Supp.2d at 421–22.
>
> "On the parties' joint motion, the district court entered final judgment of noninfringement under Rule 54(b) of the Federal Rules of Civil Procedure."

Classen, 786 F.3d at 895–96.

On May 13, 2015, the Federal Circuit vacated and remanded Judge Quarles' 2012 judgment of non-infringement in favor of Elan. (ECF No. 232.) In its opinion remanding this case to this Court, the Federal Circuit concluded that "the district court correctly decided that § 271(e)(1) exempts Elan's activities reasonably relating to developing clinical data on its approved drug Skelaxin® ("Skelaxin") and submitting that information to the Food and Drug Administration ("FDA") in a citizen petition and a supplemental new drug application ("sNDA")." *Classen*, 786 F.3d at 894. However, the court also found that because Judge Quarles' opinion did not address Plaintiff's "assert[ion] that certain activities that occurred after the FDA submissions infringed the '472 patent and that those activities are not exempt under the safe harbor of § 271(e)(1)," remand was appropriate. *Id.* Accordingly, the sole question now before this court is whether Elan's "post-submission activities constituted infringement of the '472 patent or whether they were exempt under the safe harbor." *Id.* at 898-99.

This case was transferred to the undersigned on January 22, 2016 following Judge Quarles' retirement from the bench. A new Scheduling Order (ECF No. 248) was issued, and, consistent with that Order, Elan filed its now-pending Motion on March 31, 2016.

(ECF No. 249.) The Court conducted a hearing on September 22, 2016, and the matter is fully ripe for the Court's resolution. (ECF No. 252.)

STANDARD OF REVIEW

Rule 56 of the Federal Rules of Civil Procedure provides that a court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A material fact is one that "might affect the outcome of the suit under the governing law." *Libertarian Party of Va. v. Judd*, 718 F.3d 308, 313 (4th Cir. 2013) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Thus, summary judgment is proper "only when no 'reasonable jury could return a verdict for the nonmoving party.'" *Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1257 (Fed. Cir. 2001) (quoting *Anderson*, 477 U.S. at 255)). When considering a motion for summary judgment, a judge's function is limited to determining whether sufficient evidence exists on a claimed factual dispute to warrant submission of the matter to a jury for resolution at trial. *Anderson*, 477 U.S. at 249.

In undertaking this inquiry, this Court must consider the facts and all reasonable inferences in the light most favorable to the nonmoving party. *Libertarian Party of Va.*, 718 F.3d at 312; *see also Scott v. Harris*, 550 U.S. 372, 378 (2007). However, this Court must also abide by its affirmative obligation to prevent factually unsupported claims and defenses from going to trial. *Drewitt v. Pratt*, 999 F.2d 774, 778-79 (4th Cir. 1993). If the evidence presented by the nonmoving party is merely colorable, or is not significantly probative, summary judgment must be granted. *Anderson*, 477 U.S. at 249-50. On the other hand, a

party opposing summary judgment must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986); *see also In re Apex Express Corp.*, 190 F.3d 624, 633 (4th Cir. 1999). As this Court has previously explained, a "party cannot create a genuine dispute of material fact through mere speculation or compilation of inferences." *Shin v. Shalala,* 166 F. Supp. 2d 373, 375 (D. Md. 2001) (citations omitted).

DISCUSSION

I. No Additional Discovery Is Required

At oral argument, the parties conceded that no additional factual discovery is required in order for the Court to rule on Elan's Motion. Specifically, counsel for Plaintiff indicated that now is the time to apply the law to the facts of this case. Counsel for Defendant agreed that no further discovery was needed and that the court could rule on the pending motion for summary judgment.

Although Classen argues that "the complex facts in this matter are not fully presentable to the Court in a comprehensive and understandable manner" and that "[t]he fact that the issues were remanded to the *trial court* clearly indicates that they are not ripe for summary determination but require a full, fair and comprehensive factual hearing, i.e., a trial on the merits" these arguments do not indicate what purpose additional discovery would serve. (ECF No. 250 at 7-8)(emphasis in original.)

II. The Federal Circuit's Guidance

In its decision remanding this case to this Court, the Federal Circuit offered the following guidance with respect to Plaintiff's claims:

> "To assist the district court in its analysis of infringement, if the court reaches that issue on remand, we make the following observations of the record. **Filing a patent application is generally not an infringement of a patent. It is not the making, using, offering to sell, selling, or importing of an invention.** It is the act of approaching an agency of the government in order to obtain a limited privilege and to fulfill a public goal of making knowledge of an invention available to the public. It is not commercializing an invention, which requires introducing an invention into commerce, or making preparations to do so. Moreover, infringing a multi-step method claim requires carrying out all the steps of the claim. As filing a patent application is not commercializing an invention, a method claim requiring commercialization, as claim 36 does, is likely not infringed by Elan's actions here.
>
> "In addition, **placing the information submitted to the FDA on the product label after sNDA approval generally cannot be an infringement. Information obtained from exempt activities does not cease to be exempt once the sNDA is approved.** It is a requirement of law that a drug product contains the labeling approved by the FDA. This is not to say that a pharmaceutical patent claiming a method of treatment, a method of preparation, or a composition of matter cannot be infringed by the subsequent actions of making, using, offering to sell, selling, or importing of a drug covered by that patent based on information derived from exempt activities. But that is not the case here."

Classen, 786 F.3d at 898–99 (emphasis added).

While Plaintiff interprets the Federal Circuit's use of the term "generally" to indicate that exceptions may apply to these general rules, this argument—unsupported by authority—is unpersuasive. (ECF No. 250 at 8.) Moreover, when this issue was raised during the hearing, counsel for Plaintiff was unable to indicate why the Federal Circuit's guidance should not govern this Court's analysis.[3] Accordingly, this Court is bound to

[3] Unsurprisingly, Elan expressly relies upon the Federal Circuit's guidance in support of its Motion. (ECF

follow the Federal Circuit's statement of the applicable law in its analysis of the pending Motion.

III. Plaintiff's Claims Fail as a Matter of Law

Elan argues that summary judgment is appropriate because its allegedly infringing activities are protected by 35 U.S.C. § 271(e)(1)'s safe harbor provision.[4] In addition, as set forth in its Reply and at the hearing held on its Motion, Elan argues that summary judgment is warranted because Classen "has failed to provide any evidence supporting" its allegations of infringement. (ECF No. 251 at 5, 8.)

In its Opposition, Classen argues that Elan's post-submission activities—that is, submission of clinical data to the FDA—are aimed at commercialization and thus, in Classen's view, fall outside of the safe harbor of § 271(e)(1). (ECF No. 250 at 2-4, 14-17.) The allegedly infringing activities are: (1) "reanalyzing the clinical data to identify patentable information and filing patent applications;" and (2) "making and selling Skelaxin with the revised label that contained the information derived from the clinical study." *Classen*, 786 F.3d at 897-98.

Following the Federal Circuit's guidance, it is clear that Elan's alleged "reanalyzing the clinical data to identify patentable information and filing patent applications," and

---

No. 249-1 at 13, 15.)

[4] "This provision shields drug manufacturers from patent infringement liability for using patented inventions in activities that are 'reasonably related to the development and submission of' information pursuant to the federal regulatory process of pharmaceuticals." *Classen Immunotherapies, Inc. v. Shionogi, Inc.*, 993 F. Supp. 2d 569, 576 (D. Md.), *aff'd,* 586 F. App'x 585 (Fed. Cir. 2014) (quoting *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 195 (2005)). "Congress enacted this provision of the Hatch–Waxman Act in 1984 to 'balance the need to stimulate innovation against the goal of furthering the public interest.'" *Id.* (internal citation omitted). *See also* H.R. Rep. 98–857, pt. 2, at 2714 (1984), 1984 U.S.C.C.A.N. 2686, 2714).

"making and selling Skelaxin with the revised label that contained the information derived from the clinical study" fall squarely within the safe harbor of § 271(e)(1). This conclusion is also consistent with the decision of this Court in *Classen Immunotherapies, Inc. v. Shionogi, Inc.*, 993 F. Supp. 2d 569, 578 (D. Md.), *aff'd*, 586 F. App'x 585 (Fed. Cir. 2014). In *Shionogi*, Judge Titus of this Court rejected Classen's nearly identical argument to that raised here, stating:

> "**Classen's attempts to avoid the safe harbor run aground under *Momenta*. Classen argues that its patent infringement allegations are not barred by § 271(e)(1) because its patents include claims that are "commercialization steps which are not used to develop or submit information to the FDA."** Classen admits that "[c]linical trials generate information, such as the proper manufacturing method or the proper dosage requirements or methods of treatment," and that "[t]his information is submitted to the FDA," and "thus the generation and use of this information during the clinical trials ... is protected." Nevertheless, Classen asserts that "[t]he subsequent generation and/or use of this same information during commercial sales is not protected." Classen's argument rests on its theory that "the safe harbor expires after FDA approval is obtained. If it did not, no pharmaceutical patents would ever be enforceable." Classen relies on *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011), for the proposition that the safe harbor "'does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained.'" **However, the later decision in *Momenta*[5] clarified that there is no pre/post FDA approval dichotomy under the safe harbor provision. To the extent that there is any tension between *Biogen* and *Momenta*, *Momenta* controls, as it is the more recent Federal Circuit decision. Thus, § 271(e)(1) precludes Classen's infringement claims from proceeding."**

Shionogi, 993 F. Supp. 2d at 578 (internal citations omitted) (emphasis added). Notably, *Shionogi* involved the same Plaintiff alleging a nearly identical legal theory.[6] And there, the

[5] *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012).

[6] Indeed, the *Shionogi* court cites Judge Quarles' 2006 summary judgment opinion in this case in analyzing the applicability of the § 271(e)(1) safe harbor to Classen's allegations that Shionogi infringed its now-cancelled '639 Patent by taking "commercialization steps which are not used to develop or submit information to the

Court dismissed Classen's complaint for failing to state a legally plausible claim. So, too, does this Court conclude that Classen's claims fail as a matter of law.

This Court's conclusion that Elan's post-submission activities fit within the scope of § 271(e)(1)'s safe harbor is further supported by *Telectronics Pacing Sys. v. Ventritex, Inc.,* 982 F.2d 1520, 1523–24 (Fed. Cir. 1992). As the Federal Circuit explained, *Telectronics* stands for the proposition that "the subsequent disclosure or use of *information* obtained from an exempt clinical study, even for purposes other than regulatory approval, does not repeal that exemption of the clinical study, provided that the subsequent disclosure or use is itself not an *act of infringement* of the asserted claims." *Classen*, 786 F.3d at 898 (emphasis in original) (citing *Telectronics*, 982 F.2d. at 1523-24). On this basis, the defendant in *Telectronics* remained within the safe harbor when it "present[ed] clinical trial data at a cardiology conference, report[ed] clinical trial progress to investors, analysts and journalists, and describe[ed] clinical trial results in a private fund-raising memorandum." *Id.* The alleged acts of commercialization by Elan—the filing of patent applications based on the reanalyzed clinical data and the sale of Skelaxin with the revised label containing information derived from the clinical trial—appear, contrary to Classen's argument, far less "commercial" in nature than those activities deemed protected in *Telectronics*. Accordingly, these activities remain within the scope of § 271(e)(1)'s safe harbor, and Elan is entitled to summary judgment.

FDA." *Classen Immunotherapies, Inc. v. Shionogi, Inc.*, 993 F. Supp. 2d 569, 577-78 (D. Md.), *aff'd,* 586 F. App'x 585 (Fed. Cir. 2014) (citing *Classen Immunotherapies, Inc. v. King Pharm., Inc.,* 466 F.Supp.2d 621, 623 (D.Md.2006)).

IV. Plaintiff Fails to Raise a Genuine Issue of Material Fact

Even if Classen's claims were not barred as a matter of law, Classen still fails to raise a genuine issue of material fact sufficient to preclude summary judgment. To be sure, while the burden remains on the movant to show that there is no genuine dispute of material fact and that it is entitled to judgment as a matter of law, the party opposing summary judgment must "make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

Here, with discovery long complete and this case having worn on for nearly twelve years, Classen has produced no evidence of Elan's alleged reanalysis of the data for commercial purposes so as to raise a genuine issue of material fact regarding Elan's infringement. Attached to Classen's Opposition brief are copies of Classen's and Elan's patents at issue in this case (ECF Nos. 250-1, 250-5), materials related to Dr. Classen's November 2001 presentation (ECF No. 250-2), Elan's 2001 Clinical Study Report (ECF No. 250-6), Elan's 2001 Citizen's Petition to the FDA (ECF No. 250-7), and portions of the deposition transcripts of Nancy Santilli (ECF No. 250-3) and Steve Cartt (ECF No. 250-4). While the deposition excerpts may support the inference that Ms. Santilli, Mr. Cartt, and other Elan employees attended Dr. Classen's presentation, met with Dr. Classen, and even explored the possibility of entering into a business relationship with him, these materials say nothing of Elan's alleged reanalysis of clinical study data and commercialization of that data. *See* ECF Nos. 250-3, 250-4. Thus, even if Classen's allegations were not barred as a matter of law on account of § 271(e)(1)'s safe harbor, Classen has failed to show that there exists a

genuine issue of material fact with respect to a key element of its allegations.[7] Summary judgment is therefore appropriate.

CONCLUSION

For the foregoing reasons, this 27th day of September, 2016, Elan Pharmaceuticals, Inc.'s Motion for Summary Judgment as to Non-Infringement (ECF No. 249) is GRANTED.

A separate Order follows.

__/s/_____
Richard D. Bennett
United States District Judge

[7] There does not appear to be any dispute as to whether Elan sold Skelaxin with the updated label derived from the clinical study test results. However, as set forth above, "placing the information submitted to the FDA on the product label after sNDA approval generally cannot be an infringement. Information obtained from exempt activities does not cease to be exempt once the sNDA is approved." *Classen*, 786 F.3d at 898–99.